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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,165	07/11/2003	Terence D. Butters	OGS-0002	4356

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[REDACTED] EXAMINER

DESAI, RITA J

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/618,165	BUTTERS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 16 July 2004.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.  
 4a) Of the above claim(s) 8-20 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-7 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/12/03</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

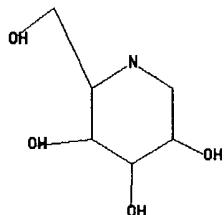
**DETAILED ACTION*****Election/Restrictions***

Applicants elected group I drawn to compounds of formula I wherein R is an alkyl group.

Applicant's traversal is not convincing. Applicants core is not novel.

A preliminary search done on the core gave numerous iterations indicating that the core is not novel and is not the applicants contribution over the prior art of record.

See below.



100.0% PROCESSED  
INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)

SEARCH TIME: 00.00.01

PROJECTED ITERATIONS: 7914 TO 10486

The search was incomplete and hence restriction is proper.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1625

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's claim has "prodrugs" and it is unclear what other groups and at what positions these groups are located, especially since applicants claim is drawn to a specific R and S configuration compound.

Applicants can overcome this by inserting the "esters thereof" in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-5, 7 are rejected under 35 U.S.C. 102(b ) as being anticipated by XP -001055984 5/2000. Mellor et al.

The reference discloses the 2 and 5 S configuration poly hydroxy piperdines.

On page 139.

Art Unit: 1625

Compound	Structure	Retention Time (min)
N-Butyl-deoxyjirimycin		12.38
N-Butyl-D-xylojirimycin		12.33
N-Butyl-D-idojirimycin		14.12
N-Butyl-D-galactojirimycin		21.52
N-Butyl-L-imino-arabinose		12.82

It clearly discloses the 2 and 5 S configuration with an alkyl chain of C4.

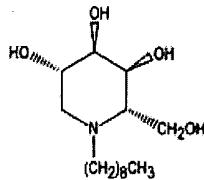
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 2001010429

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the

reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.



The reference clearly discloses

N-nonyl-alrostatin

in figure 1.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

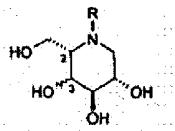
Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Mellor et al XP 001055984

The applicants compounds are drawn to

Art Unit: 1625

## 1. A compound of formula (I) or a pharmaceutically acceptable salt or prodrug thereof:



wherein

R' is C<sub>1-16</sub> straight or branched-chain alkyl, optionally substituted by C<sub>3</sub>-cycloalkyl, and optionally interrupted by -O- the oxygen being separated from the ring nitrogen by at least two carbon atoms, or C<sub>1-16</sub> alkylaryl where aryl is phenyl, pyridyl, thiophenyl or furyl wherein phenyl is optionally substituted by one or more substituents selected from F, Cl, Br, CF<sub>3</sub>, OCF<sub>3</sub>, OR', and C<sub>1-6</sub> straight or branched-chain alkyl; and

R' is hydrogen, or C<sub>1-6</sub> straight or branched-chain alkyl;

The elected group is restricted to R' being an alkyl chain.

## Determination of the scope and content of the prior art (MPEP §2141.01)

The prior art Mellor et al teaches the various R and S configuration of the piperidine polyhydroxy compounds.

See (102 rejection above) page 139 of the reference.

These compounds are for pharmaceutical use too.

The reference does disclose the structurally related 2S and 3R in the 5 membered ring.

## Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference is that the reference does not specifically disclose the 2S,3R,4R,5S configuration.

## Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Art Unit: 1625

Since several different configurations are disclosed in the prior art except the 3 R configuration , , it would be obvious to one of skill in the art and would have been motivated to make that configuration.

***Conclusion***

Claims 1-7 are not found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684.

The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625

R.D.  
August 20, 2004

*R.J.Desai*  
8/20/04